SUPPORT FOR THE AMENDMENTS

The specification has been amended to replace section headings, correct a typographical error, and to replace the Abstract. Newly-added Claims 62-88 are supported by the specification at and the original claims. No new matter is believed to have been added to the present application by the amendments submitted above.

REMARKS

Claims 62-88 are pending. Favorable reconsideration is respectfully requested.

The present invention relates to a reagent for selective quantitative determination of cholesterols comprising, separately or as a mixture:

a compound selected from the group consisting of saponins, polyenes, cholesterol derivatives, phospholipid derivatives, bacitracin, polymyxin, suzucasylin and gramicidin;

a surfactant selected from the group consisting of polyoxyethylene (10) octyl phenyl ether, polyoxyethylene higher alcohol ether, polyoxyethylene alkylene phenyl ether, polyoxyethylene tribenzyl phenyl ether, heptane sulfonic acid and octane sulfonic acid; and

an ezymatic reagent for determining cholesterol selected from the group consisting of (1) cholesterol esterase and cholesterol oxidase and (2) cholesterol esterase and cholesterol dehydrogenase.

See Claim 62.

The rejection of the claims under 35 U.S.C. §102(b) over Nagasaki et al. is respectfully traversed. That reference fails to disclose the claimed reagent.

Nagasaki et al. disclose a method of measuring the activity of lecithin cholesterol acyl transferase by determining the amount of free cholesterols. The reference describes the following methods of determining free cholesterol: (a) a colorimetric method using a combination of digitonin with another reagent and (b) an enzymatic method using cholesterol oxidase.

Nagasaki et al. fail to disclose combining those two, and even if they are used in combination, since the principles of the two methods are so different, it will not be possible to accurately determine the amount of cholesterol. Further, the reference fails to describe the use of cholesterol oxidase.

In view of the foregoing, Nagasaki et al. fail to disclose the claimed reagent. Accordingly, withdrawal of this ground of rejection is respectfully requested.

The rejection of the claims under 35 U.S.C. §103(a) over Nagasaki et al. and Nakamura et al. is respectfully traversed.

Nakamura et al. describe the use of specific surfactants in a quantitative analysis of LDL cholesterol, but fails to disclose the use of a saponin. Nagasaki et al. fail to disclose the claimed reagent, as discussed above. Accordingly, the combination of Nagasaki et al. and Nakamura et al. fails to suggest the reagent as specified in Claim 62. Withdrawal of this ground of rejection is respectfully requested.

The rejection of the claims under 35 U.S.C. §103(a) over Miyashita et al. and Nakamura et al. is respectfully traversed. Those references fail to suggest the claimed reagent.

Miyashita et al. disclose a quantitative determination of cholesterol in which the amount of digitonide produced by reaction of cholesterol with digitonin is determined by a nephelometric method. However, Miyashita et al. invented the nephelometric method that does not use an enzyme, so that the nephelometric method solves problems associated with the enzymatic method. In fact, at page of the reference, Miyashita et al. state:

> The enzymatic method, in which an oxidizing indicator is oxidized with hydrogen peroxide in the presence of peroxidase to generate color, in inevitably affected by a reductive substance in a biological sample, for example, ascorbic acid, glutathione, and bilirubin. In addition, the use of expensive enzymes imposes a significant economic burden on the enzymatic method.

Thus, since Miyashita et al. recognize that the enzymatic method has a problem, there is no motivation to combine an enzymatic method with the method described by Miyashita et al.

Nakamura et al. merely describe the use of specific surfactants in a quantitative analysis of LDL cholesterol. The method relies on enzymes. Therefore, there is no motivation to combine the methods described by Miyashita et al. and Nakamura et al.

In view of the foregoing, the claimed reagent is not suggested by Miyashita et al. and Nakamura et al. Accordingly, withdrawal of this ground of rejection is respectfully requested.

The rejections of the claims under 35 U.S.C. 112, first and second paragraphs, are believed to be obviated by the amendments submitted above, as discussed with the Examiner. Accordingly, withdrawal of those grounds of rejection is respectfully requested.

The objections to the specification and the claims are believed to be obviated by the amendments submitted above. Section heading have been replaced and typographical errors have been corrected.

Applicants submit that the present application is in condition for allowance. Early notice to this effect is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Norman F. Oblon

James J. Kelly, Ph.D.
Attorney of Record
Registration No. 41,504

Customer Number
22850

Tel: (703) 413-3000
Fax: (703) 413 -2220
(OSMMN 06/04)